COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 11-I-2008
C(2008)157

NOT FOR PUBLICATION

COMMISSION DECISION

of 11-I-2008

amending the marketing authorisation for "Thelin - Sitaxentan sodium", a medicinal product for human use, granted by Decision C(2006)3721

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

COMMISSION DECISION

of 11-I-2008

amending the marketing authorisation for "Thelin - Sitaxentan sodium", a medicinal product for human use, granted by Decision C(2006)3721

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1],

Having regard to Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation falling within the scope of Council Regulation (EEC) No 2309/93[2], and in particular the third subparagraph of Article 4 (5) and the first subparagraph of Article 5 (7) thereof,

Having regard to the notifications submitted by Encysive (UK) Limited under Article 4(1) and Article 5(1) of Regulation (EC) No 1085/2003,

Whereas:

(1) Between 10 April 2007 and 10 October 2007, the European Medicines Agency acknowledged the validity of the type IA notification(s) and accepted the type IB variation(s) submitted. It informed the marketing authorisation holder accordingly and prepared a list of the notification(s). The variation(s) took effect from the date of the communication of the acknowledgement of validity or acceptance by the European Medicines Agency / within 30 days of the date of acknowledgement, by the European Medicines Agency, of receipt of the valid notification(s).

(2) The marketing authorisation should be updated, and Decision C(2006)3721 of 10 August 2006 amended accordingly.

(3) For the sake of clarity and transparency, it is advisable, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C(2006)3721 should therefore be replaced,

[1] OJ L 136, 30.4.2004, p. 1, Regulation as amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p.1).
[2] OJ L 159, 27.6.2003, p. 24.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2006)3721 is amended as follows:

1) The following list of notifications for minor variations is added to the updated marketing authorisation.

Application number	Scope (EU numbers affected)
EMEA/H/C/679/IA/07	8.b.1 (IA) (EU/1/06/353/001-005)
EMEA/H/C/679/IB/011	42.a.1 (IB) (EU/1/06/353/001-005)

2) Annex I is replaced by the text set out in Annex I to this Decision;

3) Annex II is replaced by the text set out in Annex II to this Decision;

4) Annex III B is replaced by the text set out in Annex III B to this Decision.

Article 2

This Decision is addressed to Encysive (UK) Limited, Alder Castle House, 10 Noble Street, London EC2V 7QJ, United Kingdom.

Done at Brussels, 11-I-2008

For the Commission
Heinz ZOUREK
Director-General